zone." Also, claim 7 of the application as filed stated "Transferring device according to claim 3, characterized in that the upper part (14) of the body (11) is provided with a weakened zone." Applicants respectfully request that this objection be withdrawn.

In the Claims

35 USC §112 Rejections

The Examiner rejected claims 22-36 under 35 USC 112, first paragraph. The subject matter in these claims is the same subject matter to which the Examiner addressed the objection to the specification under 35 USC 132 as introducing new matter, so Applicants respectfully traverse this rejection. To support Applicants' arguments that the connecting device, the system comprising a percutaneous bone-anchored transferring device and a connecting device, and methods were disclosed in the application as filed, Applicants have marked up claims 22-36 to provide specific references in {} to the subject matter of the application as filed. These references are not meant to exhaustively show every reference in the original application for a particular element; however, Applicants believe that these will be sufficient to show the Examiner the support for these elements.

Claims 22-36 with references to original application.

22. A connecting device to be used in conjunction with a percutaneous bone-anchored transferring device {3}, the percutaneous bone-anchored transferring device having an annular body member {11} manufactured of a tissue-compatible material, the annular body member comprising a cavity, an interior surface, an exterior surface, an upper part {14} and a bottom part {17}, wherein the cavity extends from the upper part to the bottom part, and wherein the surface of the annular body member inside the cavity is defined as the interior surface, and wherein the surface of the annular body member outside of the cavity is defined as the exterior surface, and having radial arms {12} extending radially outward from the annular body member along a line defining the transition between the upper part {14} and the bottom part {17}, wherein the radial

arms are manufactured of a tissue-compatible material, and wherein one or more of the radial arms contains at least one hole {13}, said connecting device comprising:

a first connection unit {21}, wherein the first connection unit comprises: {Fig. 5 shows features and positioning}

a wall member defining a substantially cylindrical cavity, said cylindrical cavity having an open top and a partially-closed bottom; and

a flange extending outward around a circumference of the wall member,

wherein the wall member is shaped to fit at least partially inside the bottom part of the percutaneous bone-anchored transferring device such that the open top is introduced into the cavity of the bottom part {17} of the percutaneous bone-anchored transferring device and the partially-closed bottom abuts {23} the exterior surface {19} of the bottom part of the percutaneous bone-anchored transferring device, and wherein the partially-closed bottom contains a side opening {25};

a middle connecting unit {31}{see figure 6}, wherein said middle connecting unit is a substantially cylindrical holder, with a first end and a second end and an opening extending completely through from the first end through the second end, designed to fit inside the cavity of the upper part {14} of the percutaneous bone-anchored transferring device such that the first end is positioned near the first connection unit {21}{fig 7 shows positioning}; and

an outer contact unit {41} {fig 7 shows positioning}, wherein said outer contact unit is a substantially cylindrical holder having a lower end and an upper end, wherein the lower end is designed to fit inside the cavity of the upper part {14} of the percutaneous bone-anchored transferring device such that the lower end is positioned near the second end of the middle connecting unit {31}, and wherein the upper end is designed to reside above the upper part {14}

of the percutaneous bone-anchored transferring device.

23. The connecting device of claim 22, wherein said flange on the first connection unit {21} has a triangular cross section with the base of the triangular cross section contiguous with the wall member and the apex extending radially outward from the wall member such that the apex is extending its maximum amount near the partially-closed bottom, and wherein a limiting surface {19} is provided within the interior surface of the bottom part of the percutaneous bone-anchored transferring device by contouring the cavity near its entrance to form an outwardly increasing diameter of the cavity, such that when the open top is introduced into the cavity of the bottom part of the percutaneous bone-anchored transferring device, the flange abuts {23} to the limiting surface of the percutaneous bone-anchored transferring device. {Fig. 5 shows positioning}

24. The connecting device of claim 22, wherein the flange is disposed on the wall member such that the bottomward side of the triangle section forms a taper at the bottom of the connecting device. {Fig. 5}{21}

25. The connecting device of claim 22, wherein in the first connection unit {21} the open top of the wall member is releasably connected to the interior surface of the percutaneous bone-anchored transferring device using a screw joint and locking nut. {22}{Fig. 5}

26. The connecting device of claim 22, wherein in the first connection unit the open top of the wall member is provided with a membrane. {83} {Fig. 11}

27. The connecting device of claim 22, wherein the outer contact unit {41} is releasably arranged in the middle connecting unit {31} such that the outer contact unit {41}and the middle connecting unit {31} will be released from each other at a predetermined load on the outer contact unit. {page 1, lines 23-25}{page 8, lines 6-8}{page 11, lines 26-29}{claim 12}

28. The connecting device of claim 22, wherein the opening of the middle connecting unit {31}{fig. 6} is provided with a membrane. {82}{fig. 11}

29. The connecting device of claim 22, wherein the middle connecting unit contains a circular groove extending all the way around the middle connecting unit. {31}{fig. 6}

30. The connecting device of claim 22, wherein the middle connecting unit contains slotted radially spring-biased arms that rest against the interior surface of the upper part of the percutaneous bone-anchored transferring device. {Fig. 9}

31. The connecting device of claim 22, wherein the middle connecting unit comprises a number of electrically conductive contact sheets for obtaining an electrical transfer. {Fig. 6}{32, 33, 34}

32. The connecting device of claim 22, further comprising:

{Fig. 7 shows positioning of each element}
an electrical connection unit {24}{Fig. 5} having an upper surface and a lower surface, wherein the electrical connection unit is arranged inside the first connection unit {21} such that a set of cables extending from the lower surface of the electrical connection unit is drawn out through the side opening {25} of the first connection unit {21} and electrically conductive elements extend from the upper surface of the electrical connection unit;

{Fig. 2 shows placement}
a second connection unit {26}{Fig. 6} comprising electrically conductive contacts on a first side and a positive pole {26p}, a negative pole {26m}, and a signal pole {26s} on a second side, wherein the electrically conductive contacts on the first side contact the electrically conductive elements of the upper surface of the electrical connection unit {24} such that an electrical connection is formed between the electrical connection unit {24} and the second connection unit {26}, and wherein the second connection unit {26} is in turn introduced into first end of the

middle connecting unit {31}; and

{Fig. 7 shows placement}
three different poles (a positive pole {32}, a negative pole {34}, and a signal pole {33}) arranged around the second end of the middle connecting unit {31} and connected to the corresponding poles on the second side of the second connection unit {26} and connected via metal sheets or pins {42, 44, 43 (not shown)} to the outer contact unit {41}.

33. A system comprising a percutaneous bone-anchored transferring device and a connecting device, wherein

the percutaneous bone-anchored transferring device {3} comprises:

an annular body member {11} manufactured of a tissue-compatible material, the annular body member comprising a cavity, an interior surface, an exterior surface, an upper part {14} and a bottom part {17}, wherein the cavity extends from the upper part to the bottom part, and wherein the surface of the annular body member inside the cavity is defined as the interior surface, and wherein the surface of the annular body member outside of the cavity is defined as the exterior surface; and

radial arms {12} extending radially outward from the annular body member along a line defining the transition between the upper part {14} and the bottom part {17}, wherein the radial arms are manufactured of a tissue-compatible material, and wherein one or more of the radial arms contains at least one hole {13}, and

The connecting device comprises:

a first connection unit {21}{Fig. 5}, wherein the first connection unit comprises:

a wall member defining a substantially cylindrical cavity, said cylindrical cavity having an open top and a partially-closed bottom; and

a flange extending outward around a circumference of the wall member,

wherein the wall member is shaped to fit at least partially inside the bottom part of the percutaneous bone-anchored transferring device such that the open top is introduced into the cavity of the bottom part {17} of the percutaneous bone-anchored transferring device {3} and the partially-closed bottom abuts {23} the exterior surface {19} of the bottom part of the percutaneous bone-anchored transferring device, and wherein the partially-closed bottom contains a side opening {25};

a middle connecting unit {31}{Fig. 7}, wherein said middle connecting unit is a substantially cylindrical holder, with a first end and a second end and an opening extending completely through from the first end through the second end, designed to fit inside the cavity of the upper part of the percutaneous bone-anchored transferring device {3} such that the first end is positioned near the first connection unit {21}; and

an outer contact unit {41}, wherein said outer contact unit is a substantially cylindrical holder having a lower end and an upper end, wherein the lower end is designed to fit inside the cavity of the upper part {14} of the percutaneous bone-anchored transferring device such that the lower end is positioned near the second end of the middle connecting unit {31}, and wherein the upper end is designed to reside above the upper part {14} of the percutaneous bone-anchored transferring device.

34. A method for percutaneously transferring electrical signals or energy to and/or from an implanted unit or for the administration of a chemical or evacuation or airing of internal cavities using a system comprising a percutaneous bone-anchored transferring device and a connecting

device, wherein

{descriptions of method can be found at page 1, lines 6-17 and 20-25; page 5, lines 16-31; page 6, lines 1-31; page 7, lines 1-31; page 8, lines 1-8 and 16-29}

the percutaneous bone-anchored transferring device {3} comprises:

an annular body member {11} manufactured of a tissue-compatible material, the annular body member comprising a cavity, an interior surface, an exterior surface, an upper part {14} and a bottom part {17}, wherein the cavity extends from the upper part to the bottom part, and wherein the surface of the annular body member inside the cavity is defined as the interior surface, and wherein the surface of the annular body member outside of the cavity is defined as the exterior surface; and

radial arms {12} extending radially outward from the annular body member along a line defining the transition between the upper part {14} and the bottom part {17}, wherein the radial arms are manufactured of a tissue-compatible material, and wherein one or more of the radial arms contains at least one hole {13}, and

The connecting device comprises:

a first connection unit {21}, wherein the first connection unit comprises:

a wall member defining a substantially cylindrical cavity, said cylindrical cavity having an open top and a partially-closed bottom; and

a flange extending outward around a circumference of the wall member,

wherein the wall member is shaped to fit at least partially inside the

bottom part of the percutaneous bone-anchored transferring device such that the open top is introduced into the cavity of the bottom part {17} of the percutaneous bone-anchored transferring device and the partially-closed bottom abuts {23} the exterior surface {19} of the bottom part of the percutaneous bone-anchored transferring device, and wherein the partially-closed bottom contains a side opening {25};

a middle connecting unit {31}, wherein said middle connecting unit is a substantially cylindrical holder, with a first end and a second end and an opening extending completely through from the first end through the second end, designed to fit inside the cavity of the upper part {14} of the percutaneous bone-anchored transferring device such that the first end is positioned near the first connection unit {21}; and

an outer contact unit {41}, wherein said outer contact unit is a substantially cylindrical holder having a lower end and an upper end, wherein the lower end is designed to fit inside the cavity of the upper part {14} of the percutaneous bone-anchored transferring device such that the lower end is positioned near the second end of the middle connecting unit {31}, and wherein the upper end is designed to reside above the upper part {14} of the percutaneous bone-anchored transferring device,

wherein the method comprises the steps of:

{Figs. 1 and 13 show placement of invention in soft tissue and bone}

placing an implanted unit {Fig. 13 – inner unit} into a subject through a bore hole {5} that has been made through soft tissue and bone of the subject; {page 5, lines 26-27; page 9, lines 30-31; page 10, lines 1-5}

connecting the implanted unit through the first connection unit {21} of the connecting device to

the middle connecting unit {31}; {page 10, lines 3-5; page 11, lines 1-3}

placing the percutaneous bone-anchored transferring device {3} over the first connection unit {21} and middle connecting unit {31} and into the bore hole {5} such that the bottom part {17} of the percutaneous bone-anchored transferring device is inside the bore hole {5} and the radial arms {12} are resting on the outer surface of the bone {1} with the tissue {2} temporarily moved to a side; {Fig. 1; claim 3, lines 16-22; page 6, lines 13-23; page 7, lines 7-22; page 10, lines 2-3}

fastening the radial arms {12} into the bone {1}; {Fig. 1; page 9, line 31; page 10, lines 1-3 and 7-11}

connecting the outer contact unit {41} to the middle connecting unit {31}; {Claim 9; Page 11, lines 13-15}

connecting the outer contact unit {41} to an outer device {Fig. 13 – outer unit; Page 1, lines 9-11; Page 1, lines 13-15}; and

activating the outer device to transfer electrical signals or energy to and/or from the implanted unit or to administer a chemical through the implanted unit or to evacuate or air internal cavities through the implanted unit. {Claims 1, 3 and 10; page 1, lines 6-7 and 13-17; page 5; lines 16-24; page 8, lines 10-29; page 12, lines 18-24}

35. A method for using a system comprising a percutaneous bone-anchored transferring device and a connecting device, wherein

{descriptions of method can be found at page 1, lines 6-17 and 20-25; page 5, lines 16-31; page 6, lines 1-31; page 7, lines 1-31; page 8, lines 1-8 and 16-29} {Figs. 1 and 13 show application}

the percutaneous bone-anchored transferring device {3} comprises:

an annular body member {11} manufactured of a tissue-compatible material, the annular body member comprising a cavity, an interior surface, an exterior surface, an upper part {14} and a bottom part {17}, wherein the cavity extends from the upper part to the bottom part, and wherein the surface of the annular body member inside the cavity is defined as the interior surface, and wherein the surface of the annular body member outside of the cavity is defined as the exterior surface; and

radial arms {12} extending radially outward from the annular body member {11} along a line defining the transition between the upper part {14} and the bottom part {17}, wherein the radial arms {12} are manufactured of a tissue-compatible material, and wherein one or more of the radial arms contains at least one hole {13}, and

The connecting device comprises:

a first connection unit {21}, wherein the first connection unit comprises:

a wall member defining a substantially cylindrical cavity, said cylindrical cavity having an open top and a partially-closed bottom; and

a flange extending outward around a circumference of the wall member,

wherein the wall member is shaped to fit at least partially inside the bottom part of the percutaneous bone-anchored transferring device such that the open top is introduced into the cavity of the bottom part {17} of the percutaneous bone-anchored transferring device {3} and the partially-closed bottom abuts {23} the exterior surface {19} of the bottom part of the percutaneous bone-anchored transferring device, and wherein the partially-closed bottom contains a side

opening {25};

a middle connecting unit {31}, wherein said middle connecting unit is a substantially cylindrical holder, with a first end and a second end and an opening extending completely through from the first end through the second end, designed to fit inside the cavity of the upper part {14} of the percutaneous bone-anchored transferring device such that the first end is positioned near the first connection unit {21}; and

an outer contact unit {41}, wherein said outer contact unit is a substantially cylindrical holder having a lower end and an upper end, wherein the lower end is designed to fit inside the cavity of the upper part {14} of the percutaneous bone-anchored transferring device such that the lower end is positioned near the second end of the middle connecting unit {31}, and wherein the upper end is designed to reside above the upper part {14} of the percutaneous bone-anchored transferring device,

wherein the method comprises the steps of:

connecting an implanted unit {Fig. 13 – inner unit}, which has been placed into a subject through a bore hole {5} made through soft tissue {2} and bone {1} of the subject, through the first connection unit {21} of the connecting device to the middle connecting unit {31}; {page 5, lines 26-27; page 9, lines 30-31; page 10, lines 1-5; page 11, lines 1-3}

placing the percutaneous bone-anchored transferring device {3} over the first connection unit {21} and middle connecting unit {31} and into the bore hole {5} such that the bottom part {17} of the percutaneous bone-anchored transferring device is inside the bore hole {5} and the radial arms {12} are resting on the outer surface of the bone {1} with the tissue {2} temporarily moved to a side; {Fig. 1; claim 3, lines 16-22; page 6, lines 13-23; page 7, lines 7-22; page 10, lines 2-3}

fastening the radial arms {12} into the bone {1}; {Fig. 1; page 9, line 31; page 10, lines 1-3 and 7-11}

connecting the outer contact unit {41} to the middle connecting unit {31} {Claim 9; Page 11, lines 13-15}; and

connecting the outer contact unit {41} to an outer device {Fig. 13 – outer unit; Page 1, lines 9-11; Page 1, lines 13-15}.

36. The method of claim 35, comprising the additional steps of:

disconnecting the outer contact unit from the middle connecting unit {31};

placing a lid {Fig. 10} {61} over the upper part {14} of the percutaneous bone-anchored transferring device; and

placing the soft tissue {2} over the lid {61}. {Page 6, lines 24-28; page 12, lines 5-8}

End of marked up claims.

Applicants respectfully submit that the connecting device, the system comprising a percutaneous bone-anchored transferring device and a connecting device, and methods were disclosed in the application as filed, and that the amendments made to the specification and claims merely clarify information that was inherent in the original disclosure. Applicants respectfully request that this rejection be withdrawn and claims 22-36 be allowed.

The Examiner rejected claim 15 under 35 USC 112, second paragraph, as being indefinite. Applicants respectfully traverse this rejection. As explained on page 10, lines 22-25, of the specification, "The upper part 14 of the percutaneous bone anchored transferring device is thinned to allow deformation if a large load should occur on the percutaneous bone anchored

transferring device. This provides a weakened zone." The weakened zone is weak relative to the areas of the percutaneous bone anchored transferring device that are adjacent to the weakened zone, such that if a force were exerted on the outer part of the percutaneous bone anchored transferring device, the device would absorb the force by deforming at the weakened zone rather than transmitting the force to surrounding bone or other tissue. The requisite degree of thinning the upper part of the device to create a weakened zone is that which would be sufficient to allow deformation in the weakened zone if a force is exerted on the percutaneous bone anchored transferring device that would be sufficient to cause damage to surrounding bone and tissue if not for the weakened zone absorbing the force. Applicants wish to point to the case *Orthokinetics Inc. v. Safety Travel Chairs Inc.*, where in the claims for a wheelchair, the language "so dimensioned as to be insertable through the space between the door frame of an automobile" was challenged as being indefinite. The Court of Appeals for the Federal Circuit rejected the challenge, noting that while the claim requires one to measure the space between a selected auto's door frame and seat and then "dimension" the legs of the wheelchair so that they will fit in that space in that particular make of automobile, one of ordinary skill in the art could easily determine the appropriate dimension. *Orthokinetics Inc. v. Safety Travel Chairs Inc.*, 806 F.2d 1565, 1576, 1 USPQ2d 1081, 1088 (Fed. Cir. 1986). In the present case, the specification provides the standard for ascertaining the requisite degree of thinning that would need to occur to create the weakened zone, and one of ordinary skill in the art would be reasonably apprised of the scope of the invention. Applicants respectfully request that this rejection be withdrawn and claim 15 be allowed.

The Examiner rejected claims 22-32 under 35 USC 112, second paragraph, as being indefinite. Applicants respectfully traverse this rejection. The Examiner believes "percutaneous bone-anchored transferring device" to be functional language. Applicants have chosen to name their invention percutaneous bone-anchored transferring device instead of just "device." The use of the term is as a noun and not as a functional term. "In drafting the claims, the inventor may be his own 'lexicographer' when there is a need to coin new expressions with which to precisely delineate a new technological development." *ZMI Corp. v. Cardiac Resuscitator Corp.*, 844 F.2d 1576, 6 USPQ2d 1557, 1560 (Fed. Cir. 1988). Applicants respectfully request that this

rejection be withdrawn and claims 22-32 be allowed.

35 USC §102 Rejection

The Examiner rejected claims 13-21 as being anticipated by Ray (US Patent 4,328,813). Applicants respectfully traverse this rejection. The Examiner states that Ray discloses a percutaneous bone-anchored transferring device comprising an annular body member comprising a cavity, an interior surface, an exterior surface, an upper part and a bottom part, radial arms extending radially outward from the annular body member, and a lip in the interior surface of the upper part (Figures 1-4).

The percutaneous bone-anchored transferring device as described in Applicants' invention is comprised of an annular body member with radial arms, some of which contain at least one hole. The purpose of the radial arms is to steady the device against the outer bone surface. The holes in the radial arms allow the radial arms to be attached to the bone by means of a screw or the like. All of the claims of Applicants' invention involving the percutaneous bone-anchored transferring device (claims 13-21) contain those limitations.

Ray discloses a system comprising a socket means and a plug means. Ray discloses two means for anchoring his socket means to the bone into which it is inserted. One of the means is threading contained on the outer surface of the socket means that can engage the bone on the inner surface of the burr hole. The other means is for the socket means to contain a split and to be made of a flexible material biased to maintain the split, such that the two sides of the split can be brought together while the socket means is being inserted into the bone. Once the socket means is inserted into the bone, the socket means is released so as to allow the split to open to its normal bias to the extent that the burr hole will allow, thus causing the socket means to exert an outward pressure upon the inner surface of the burr hole to secure its position. Applicant's attorney has studied US Patent 4,328,813 including its Figures 1-4 and does not see radial arms disclosed in that reference. Thus, if the Examiner maintains that radial arms as claimed in the present invention are disclosed in the cited reference, Applicants respectfully request that the Examiner point them out specifically.

The radial arms that are securable to the bone as disclosed in Applicants' invention

provide a better means than that disclosed by Ray for securing a device in bone. The radial arms lying against the outer bone surface prevents the device from moving when being torqued from any angle. This aids in preventing irritation of the bone and tissue around the device and facilitating healing. This also helps to prevent accidental dislodging of the device. Also, Applicants' invention does not need threading to secure it to the bone; therefore, Applicants' invention can have a smaller diameter than if it contained threading and it can have an asymmetrical design, if desired. An asymmetrical design may be desired when the bone thickness at the implant site is so thin that the cables have to leave the implant in a radial direction.

The Examiner did not address additional elements of Applicants' invention as disclosed in claims 14-17 and 19-21. For example, claim 14 provides a limiting surface within the interior surface of the bottom part. Claim 15 provides a weakened zone in the upper part. Claim 16 provides a substantially circular groove on the interior surface. Claim 17 provides that the upper part comprises two parts that are releasably connected. Claim 19 provides that the radial arms are positioned above and substantially parallel with the outer bone surface and beneath the soft tissue, the one or more of the radial arms is anchored to the outer bone surface, the bottom part is positioned beneath the outer bone surface, and the upper part is positioned above the outer bone surface. Claims 20 and 21 contain the additional elements of claim 19, plus claim 20 provides that the exterior surface of the bottom part is suitably textured to allow adaptation to the bone into which it will be introduced. Claim 21 further provides that the radial arms are pivotable and bendable. The Examiner has not pointed to where these additional elements are disclosed in Ray. Applicants' attorney did not find these elements disclosed Ray. If the Examiner maintains that these elements are disclosed in Ray, Applicants' respectfully request that these elements be pointed out specifically by column and line number or figure and reference number.

As discussed in *In re Piasecki*, the examiner bears the initial burden, on review of the prior art or on any other ground, of presenting a *prima facie* case of unpatentability. *In re Piasecki*, 745 F.2d 1468, 1472, 223 USPQ 785, 788 (Fed. Cir. 1984). Applicants respectfully submit that the Examiner has not presented a *prima facie* case of unpatentability of Applicants' invention. If the Examiner cannot show that Ray discloses all of the limitations of Applicants'

invention as presented in claims 13-21, Applicants respectfully request withdrawal of this rejection and allowance of claims 13-21.

For the foregoing reasons, Applicants respectfully urge that all of the claims be allowed. Applicants' attorney requests a phone call if the Examiner requires any further clarification. The Extension fee is enclosed, but the Commissioner is authorized to charge any additional fees deemed due or refund any excess to Deposit Account No. 15-0610.

Respectfully submitted,
OPPEDAHL & LARSON, LLP

Karen L. Wade, Ph.D.
Reg. No. 52,332
Marina T. Larson, Ph.D.
Reg. No. 32,038
P.O. Box 5068
Dillon, CO 80435-5068
970-468-6600